

IN THE CLAIMS

Please amend claim 1 as indicated in the claim listing. Claim 1 now recites that the maximum particle size of the substantially pure *Spongilla lacustris* powder is 0.2 mm. Support for this amendment can be found, for example, at paragraph [0093].

REMARKS/ARGUMENTS

Claims 1, 3, 7 and 24-25 are pending in this application. Claims 2, 4-6, 8-23, and 26-27 have been previously cancelled.

Applicant respectfully requests reconsideration of this application in light of the arguments presented *infra*.

A. The Reka Farm Reference is not a Proper 35 U.S.C. §102 Prior Art Reference.

Claims 1, 3 and 24 have been rejected under 35 U.S.C. §102(b) as anticipated by Reka Farm (printed from http://www.reka-farm.ru/produ_e.htm 4/14/2008 4:53:43 PM) ("Reka Farm"). Furthermore, claims 1, 3, 7 and 24 are rejected under 35 U.S.C. § 103(a) as obvious over Reka Farm in view of Manconi et al. (2008 Global diversity of sponges (Porifera: Spongillina) in freshwater, *Hydrobiologia*, Volume 595 Page 27-33) ("Manconi"); and claims 1, 24 and 25 are rejected under 35 U.S.C. § 103(a) as obvious over Reka Farm in view of Manconi and further in view of Philippe et al. (United States patent number 7,078,047) ("Philippe"). Applicant respectfully asserts that the Reka Farm reference is not prior art under 35 U.S.C. § 102, and therefore cannot be used to establish a 102(b) or 103(a) rejection.

The Applicant sincerely appreciates Supervisory Examiner Dr. Jon Weber's time and the courtesy displayed during the May 29, 2008 telephonic interview. Dr. Weber and the Applicant's representative discussed the new 35 U.S.C. §102(b) rejection of record and the cited Reka Farm web site.

During the interview the Applicant took the position that the cited reference does not qualify as a 35 U.S.C. §102 prior art reference. The Applicant noted that a cited reference only qualifies as prior art if it meets at least one of the described statutory requirements of 35 U.S.C. § 102. (M.P.E.P. § 2141.01(I).) As detailed in 35 U.S.C. § 102:

"A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or...

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or...

(e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent..." (Emphasis added)

In the present case, the Reka Farm publication does not qualify as 35 U.S.C. §102 prior art. Reka Farm is not a prior patent or patent application and therefore does not qualify as prior art under 35 U.S.C. § 102(e). Reka Farm also does not qualify as prior art under 35 U.S.C. § 102(a) or (b) because it is not a prior art printed publication, as defined by the M.P.E.P., and it does not disclose information showing that the invention was either known or used by others in this country prior to the present invention, or in public use or on sale in this country more than one year prior to the present application filing date.

Further expounded, Reka Farm does not qualify as a prior art printed publication as defined under 35 U.S.C. § 102(a) or (b) because it was not published before September 9, 2003, the date the present application was filed. The earliest publication date the Office has provided for the Reka Farm reference is the Office's retrieval date, April 14, 2008. As explained in section 2128 of the M.P.E.P., "[p]rior art disclosures on

the Internet or on an on-line database are considered to be publicly available as of the date the item was publicly posted. Absent evidence of the date that the disclosure was publicly posted, if the publication itself does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b)" (emphasis added). Since the Office has not provided evidence of the date on which the Reka Farm publication was first publicly posted, the April 14, 2008 Office retrieval date is the only date that can be used to determine the date of publication. April 14, 2008 is not prior to September 9, 2003, the filing date of the present application, and therefore, does not qualify as a prior printed publication as defined by 35 U.S.C. § 102(a) and (b).

To verify that the referenced web site was not published before the present application, Applicant has independently searched the web site's archived history using Internet Archive's "Wayback Machine" at <http://www.archive.org>. This database provides a digital library of Internet sites and other cultural artifacts in digital form. The database includes over 85 billion web pages archived from 1996. Results from Applicant's search using Internet Archive's database have been attached hereto as Appendix A and show that the earliest recorded archive of <http://www.reka-farm.ru/> is July 6, 2007. July 6, 2007 is not prior to September 9, 2003 and therefore, still does not qualify the reference as a 35 U.S.C. § 102 prior art reference.

Reka Farm also does not qualify as a 35 U.S.C. § 102(a) or (b) prior art because it does not disclose information showing that the invention was either known or used by others in this country prior to the present invention, or in public use or on sale in this country more than one year prior to the present application filing date. Reka Farm is a Russian website. Nothing in the Reka Farm text indicates that badiaga was every known, used by others, in public use or on sale in this country at any time before the filing date of the present application. The Office has presented absolutely no evidence showing that present invention was ever known, used by others, in public use or on sale in the United States, as required by 35 U.S.C. §102(a) and 35 U.S.C. §102(b), prior to the filing of the present application. Furthermore, the Applicant notes that all of the information included in the Reka Farm web site could easily have been derived from the

present application and Applicant asserts that this may, in fact, be the case. The Office offers no evidence to the contrary.

Applicant also asserts that the Office has not demonstrated that the Russian-based Reka Farm web site was published before September 9, 2003, (the filing date of the present application and presumed invention date for 35 U.S.C. §102(a) purposes only), OR describes a use in the United States at least one year prior to September 9, 2003 (as required by 35 U.S.C. §102(b)), OR describes a use in the United States prior to the presumed invention date, September 9, 2003, (as required by 35 U.S.C. §102(a)). Therefore, Applicant respectfully asserts that Reka Farm cannot properly be used as prior art to support a 35 U.S.C. § 102(b) or 103(a) rejection, as the Office has presently done.

B. Reka Farm does not Anticipate Claims 1, 3 and 24 under 35 U.S.C. § 102(b).

In deference to the Office's assertion that Reka Farm is a valid 35 U.S.C. § 102(b) reference, the Applicant makes the following arguments in traversal of the 35 U.S.C. §102(b) rejection. The Applicant respectfully asserts that the following arguments are made without admitting to the propriety of the cited art or the 35 U.S.C. §102(b) rejection. Further, the Applicant reserves it right to appeal the propriety of the cited art and the 35 U.S.C. §102(b) rejection, if necessary.

The M.P.E.P at section 2131 states, in part, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicant asserts that aforementioned Reka Farm web site does not expressly or inherently describe each and every element set forth in the present claims.

The Office asserts that Reka Farm anticipates claim 1 of the present application and thus, has rejected claims 1, 3 and 24 under 35 U.S.C. §102(b). The Applicant respectfully disagrees. Claim 1, the only independent claim presently under consideration, as amended, is drawn to a therapeutic composition comprising a

substantially pure powder of a fresh water sponge, *Spongilla lacustris* ("*S. lacustris*"), and at least one pharmaceutically acceptable excipient, wherein the composition comprises approximately 50% to 60% insoluble material having a maximum particle size of 0.2 mm. Reka Farm does not teach each and every element set forth in the present claims. Reka Farm does not teach a substantially pure *S. lacustris* composition, wherein the composition 50% to 60% insoluble material having a maximum particle size of 0.2 mm.

According to the Office, "pharmaceutical compositions comprising substantially pure badiaga powder from *S. lacustris* in a pharmaceutically acceptable excipient are well documented in the pharmaceutical/cosmetics art for application in skin diseases and used for over a century for the skin applications." (See April 30, 2008 Office Action, page 4, lines 14-18.) However, this statement is inaccurate. Reka Farm does not disclose a "substantially pure" powder of *S. lacustris* as described at paragraphs [0090] through [0094] of the present application.

The present specification explains that freshly collected *S. lacustris* are "mucoid amorphous masses and emit a characteristic odor that most observers describe as unpleasant." (See specification, for example, paragraph [0090].) As a result, they must undergo an extensive purification and refining process before they can be incorporated into a pharmaceutical composition. (See specification, for example, paragraphs [0090] to [0095].) Reka Farm does not disclose debriement, repeated washings, controlled environment drying and carefully sizing *S. lacustris* preparations, as described in the present specification. (See specification, for example, paragraphs [0090] to [0095].) Therefore, Reka Farm does not disclose a "substantially pure" *S. lacustris* preparation. As a result, Reka Farm does not expressly or inherently describe each and every element of the present claims.

The Office also asserts that the prior art composition "must inherently comprise approximately 50% to 60% insoluble material of substantially pure powder of *S. lacustris* as is recited in the claimed invention because the prior-art-recited powder of *S. lacustris*

is also in powder form..." Applicant respectfully disagrees with this statement. Persons of ordinary skill know that powders are often fully soluble and never, *per se*, completely insoluble. Such skilled artisans would not conclude that all powders necessarily comprise approximately 50% to 60% insoluble material. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112(IV), *citing Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Reka Farm does not expressly or inherently disclose a therapeutic composition comprising approximately 50% to 60% insoluble material. The compositions described in Reka Farm may be 1%, 5% 50% 99% etc. insoluble powered; who can tell? Nowhere is the solubility of the Reka Farm power mentioned. A person skilled in the art would be left to guess what portion of the Reka Farm composition consists of insoluble powder.

According to the M.P.E.P., inherency cannot be established by probabilities or possibilities. M.P.E.P. § 2112(IV) "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112(IV), *citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis added). In the present case, the Office has merely made a conclusory statement of inherency that is unsupported by rationale or argument. The concentration of insoluble powder in the present invention, as presently claims is not necessarily present in the cited reference. Applicant respectfully asserts that Reka Farm does not disclose, either expressly or inherently, a composition comprising approximately 50% to 60% insoluble material, and therefore, does not disclose each and every element presently claimed.

Moreover, the Applicant has amended claim 1 to further define the invention by limiting the insoluble material to a size not exceeding 0.2 mm. Reka Farm does not disclose or fairly suggested this particle size and therefore, does not expressly or inherently describe each and every element of the present claims.

C. "Badiaga" does not have a Precise Definition and therefore, does not Describe, Either Literally or Inherently, the Present Invention.

The Reka Farm reference uses the ill-defined folk term "badiaga" to describe the composition offered for sale on their web site. The Office, while presenting no evidence that the Reka Farm web site's content was in the public domain at least one year before the filing of the present application, asserts that the web site is evidence that the present invention was known in the art because the web site teaches "badiaga was obtained, processed and applied even in the last century" (see the April 30, 2008 office action at page 4 first full paragraph). Thus, the Office is implying that persons skilled in the art would know that "badiaga" necessarily and always comprised a substantially pure powder of *S. lacustris*, and at least one pharmaceutically acceptable excipient, wherein said therapeutic composition comprises approximately 50% to 60% insoluble material having a maximum particle size of 0.2 mm of said substantially pure powder of *S. lacustris*, as presently claimed. However, this is not the case. "Badiaga" does not describe the presently claimed invention.

"Badiaga," like many ancient folk terms translated from regional dialects, can have many meanings. The term "badiaga" or "badyaga" is often used in folk remedies to refer to fresh water sponges. Appendix B includes five Russian publications and partial English translations thereof. Each reference is provided to demonstrate the diverse meaning the term "Badiaga" has to native Russian speakers. For example "The Big Encyclopedia of Medicine," "Dr. Uzhegov's Hadbook of Folk Medicine for Children," "Encyclopedic Dictionary," the "Encyclopedia of Medicinal Plants and Animal Products" and the "Real Encyclopedia of Medical Sciences" all define "badiaga" or "badyaga" as fresh water sponges but each ascribe a different function and use for the sponge. Each of the above mentioned sources defines the word "badiaga" as referring to fresh water sponges generally, and not to a particular species of fresh water sponges, to a therapeutic composition, or to the particular size, solubility, or purity of the powdered fresh water sponge. "Badiaga" has no scientific meaning and is not listed as an

accepted classification of any specific sponge species. The term "badiaga" has been used in folk medicine by Russian laymen for centuries without any scientifically accepted methods for taxonomical identification or characterization of the composition or its biological activity. In fact, "badiaga" is often translated as thistle. Thus, a person of ordinary skill upon seeing the Reka-Farms web site and reading the term "badiaga" would not, necessarily and always (as required by the M.P.E.P. to establish inherency), envision the present invention, a therapeutic composition of substantially pure *S. lacustris* with a very specific solubility and particle size as presently claimed.

Applicant respectfully asserts that a compelling case for withdrawal of the present 35 U.S.C. §102 (b) rejection has been made. First, the Applicant respectfully asserts that the Reka Farm reference does not qualify as an anticipatory reference because Reka Farm was not published before the filing date of the present application and does not describe a use in the United States prior to the filing date of the present application. Second, Reka Farm does not teach, either literally or inherently, each limitation in independent claim 1. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131, *citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Reka Farm does not expressly or inherently disclose a substantially pure *S. lacustris* composition, having from 50% to 60% substantially pure *S. lacustris* having a maximum particle size of 0.2 mm. Finally, Reka Farm does not expressly or inherently teach the present invention. Reka Farm teaches a folk remedy referred to as "badiaga," not the present invention. As discussed above and demonstrated in the attached references (See Appendix B), "badiaga" refers to fresh water sponges generally and to many different composition, not necessarily and always a therapeutic for treating acne as presently claimed. Thus, a person of ordinary skill in the art would not arrive at the presently claimed invention merely from the term "badiaga."

For the foregoing reasons, the Applicant respectfully requests that the 35 U.S.C. §102(b) rejection of record be withdrawn as to claims 1, 3 and 24.

C. The Combined Teachings of Reka Farm, Manconi and Philippe do not Render the Present Claims Obvious under 35 U.S.C. § 103.

Claims 1, 3, 7 and 24 have been rejected under 35 U.S.C. §103(a) as obvious over the combined teachings from Reka Farm (printed from http://www.reka-farm.ru/produ_e.htm 4/14/2008 4:53:43 PM) in view of Manconi et al. (2008 Global diversity of sponges (Porifera: Spongillina) in freshwater, *Hydrobiologia*, Volume 595 Page 27-33) ("Manconi"). Additionally, claims 1 and 24-25 have been rejected under 35 U.S.C. §103(a) as obvious over combined teachings from Reka Farm in view of Manconi and further in view of Philippe et al. (US Pat. 7,078,047) ("Philippe"). These rejections will be discussed together because they are based on the same primary reference Reka Farm.

Obviousness is a question of law based on underlying factual inquiries. MPEP § 2141(II). Support for any 35 U.S.C. § 103 rejection must include a "clear articulation of the reason(s) why the claimed invention would have been obvious." MPEP § 2142, citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007). The Office bears the initial burden of factually supporting a *prima facie* conclusion of obviousness, and if the examiner does not meet this burden, the applicant is "under no obligation to submit evidence of nonobviousness." MPEP § 2142.

In the present case, the Office uses the Reka Farm reference to support its conclusion of obviousness. To support an obviousness rejection, the cited art must qualify as prior art under 35 U.S.C. § 102. "Before answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102." M.P.E.P. § 2141.01, citing *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987). As discussed *supra*, the primary reference used to support the Office's obviousness rejections, Reka Farm, does not qualify as an anticipatory reference because *inter alia*, Reka Farm was not published before the filing date of the present application and does not describe a use in the United States prior to the filing date of the present application.

Therefore, Reka Farm is not a proper prior art reference under 35 U.S.C. § 102 and cannot be used to support either of the Office's 35 U.S.C. § 103(a) rejections. As a result, Applicant respectfully asserts that the Office has not met its burden of presenting a *prima facie* case of obviousness.

The Applicant respectfully asserts that the following arguments are made without admitting to the propriety of the 35 U.S.C. §103(a) rejections or the references cited in support of the rejections. Further, the Applicant reserves the right, if necessary, to appeal the propriety of the 35 U.S.C. §103(a) rejections or the referenced cited in support of the rejections.

Assuming *arguendo*, for the purpose of completeness, that the cited references are proper prior art references, the combined teaches of Reka Farm in view of Manconi and in further view of Philippe do not teach all the limitations presently claimed. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All the words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). The combined teachings of Reka Farm, Manconi and Philippe do not teach, either literally or inherently, each and every limitation in the only independent claim of the present application, claim 1.

Specifically, Reka Farm does not disclose a substantially pure *S. lacustris* composition, having from 50% to 60% insoluble material with a maximum particle size of 0.2 mm. The deficiencies in Reka Farm are not remedied when Reka Farm is combined with Manconi and/or Philippe. Neither Manconi nor Philippe teach or fairly suggest a substantially pure powder of *S. lacustris* having from 50% to 60% insoluble material with a maximum particle size of 0.2 mm. Additionally, nothing in either Manconi or Philippe would suggest modifying the Reka Farm teachings to achieve the presently claimed invention. Therefore, the combination of references, Reka Farm in view of Manconi, or Reka Farm in view of Manconi and further in further view of Philippe

et al fail to teach or fairly suggest all of the limitations of the presently claimed invention and would not lead a person of ordinary skill in the art to arrive at the invention as presently claimed in claims 1, 3, 7 and 24-25.

The Office must not resort to hindsight reasoning based on the Applicant's disclosure. As explained in the M.P.E.P., impermissible hindsight (e.g., hindsight based on Applicant's disclosure or other information known to skilled artisans after the filing date of the present application) must be avoided; the legal conclusion of obviousness must be reached on the basis of the facts gleaned only from the prior art and used to evaluate the subject matter as a whole. MPEP § 2142 (emphasis added). In the present case, the cited art clearly does not disclose all the elements of the claimed invention. A substantially pure powder of *S. lacustris* having from 50% to 60% insoluble material with a maximum particle size of 0.2 mm is not taught in Reka Farm, Manconi, Philippe, or the combination of Reka Farm, Manconi and Philippe. A hypothetical skilled artisan at the time of present invention presented with only the cited references would not have arrived at the claimed invention. It is the Office's use of impermissible hindsight and not the disclosure of the cited references that has lead to the improper conclusion of obviousness.

Moreover, the Office cannot substantiate the assertion that because Reka Farm teaches a folk remedy called "badiaga" it inherently teaches the present invention. The presently claimed invention is a therapeutic composition comprising approximately 50% to 60% insoluble material having a maximum particle size of 0.2 mm of substantially pure powder of *S. lacustris*. As demonstrated in the attached references, "badiaga" does not have a single accepted definition and is often used to refer to different species of sponges or even to thistle (i.e. a family of flowering plants, mostly in the *Asteraceae* family) (See Appendix B and C). A person of ordinary skill in the art could not reasonably be expected to succeed in making the present invention because the term "badiaga" does not disclose the exact composition and nature of its ingredients.

Further, the secondary references do not tie the term "badiaga" to a substantially pure powder of *S. lacustris* having a particle size no greater than 0.2 mm or a composition containing from 50% to 60% insoluble powder. Consequently, the skilled person would have to perform unreasonable, trial and error experimentation without any reasonable probability of successfully achieving the claimed invention.

Therefore, the Applicant respectfully asserts that the Office has not established that the cited references collectively teach or fairly suggest each limitation of the claimed invention. A person of ordinary skill in the art would not be motivated to modify Reka Farm (the primary reference) based on the teachings of the secondary references to arrive at the present invention. Finally, the historically ambiguous meaning of the term "badiaga" combined with the incomplete teachings in the secondary references would necessitate trial and error experimentation that would be highly unpredictable and cause undue experimentation for the person of ordinary skill in the art in attempting to arrive at the present invention. Therefore, the Applicant respectfully asserts that the Office has not established a *prima facie* case of obviousness and respectfully request that the 35 U.S.C. §103(a) rejections of record as to claims 1, 3, 7, 24 and 25 be withdrawn.

Conclusion

The Applicant believes that this response to the Office Action is complete and that the present case is now ready to be passed to allowance. Applicant appreciates the Examiner's diligence in regards to this important application. Thus, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

Dated: October 16, 2008

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